DEPARTMENT OF HEALTH AND HUMAN SERVICE 95053d Public Health Service

Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

October 21, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
Ref. KAN 2005-02

Mr. Jerry D. Suther, President
Suther Feeds, Inc.
105 S. Kansas Ave.
Frankfort, KS 66427-1331

Dear Mr. Suther:

An investigation of your medicated feed mill conducted by a Food and Drug Administration investigator on August 11, 13 & 18, 2004, found significant deviations from current Good Manufacturing Practice (cGMP) regulations for Medicated Feeds (Title 21, Code of Federal Regulations, Part 225). Such deviations cause feeds being manufactured at this facility to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act. Our investigation found deviations including, but not limited to, the following:

Equipment that comes in contact with active drug components and feeds in process is not subject to all reasonable and effective procedures to prevent unsafe contamination of manufactured feed. [21 CFR 225.65(b)]

Sequential production of medicated feeds is not done on a predetermined basis designed to prevent unsafe contamination of feeds with residual drugs. [21 CFR 225.65(b)(3)]

Failure to investigate and implement corrective action when assay results show medicated feeds are not within permissible assay limits. [21 CFR 225.58(d)]

Failure to consistently and adequately control the receipt, storage, and inventory of drug products. For instance:

- Failure to reject incoming drugs which have been subjected to adverse conditions which may have adversely affected their identity, strength, quality or purity. [21 CFR 225.42(b)(1)]
- Drug receipt records do not accurately indicate the identity, quantity, and condition of the drug when received, and return of any damaged drugs for each lot of drug received. [21 CFR 225.42(b)(5)]
- Failure to maintain an accurate daily inventory record for each drug used in the manufacture of medicated feeds. [21 CFR 225.42(b)(6)]

- Failure to investigate and take corrective action for a significant discrepancy between actual drug usage and theoretical drug usage. [21 CFR 225.42(b)(7)]

Failure to maintain master records and batch production records as required. [21 CFR 225.102(b)] For instance:

- The Master Record File does not contain a current copy or description of the label that will accompany the medicated feed. [21 CFR 225.102(b)(1)(iii)]
- The batch production records are not checked by a responsible individual at the end of the working day to determine whether all required production steps have been performed. [21 CFR 225.102(b)(4)]

Failure to maintain distribution records for each shipment of medicated feed. [21 CFR 225.110(b)]

Failure of your firm's mixer/blender study to demonstrate your equipment's capability to produce a medicated feed of intended potency. [21 CFR 225.30(b)(1)

Failure to maintain equipment in a reasonably clean and orderly manner. [21 CFR 225.30(b)(2)]

The above is not intended as an all-inclusive list of cGMP violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these cGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these cGMP violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License under section 512(m)(4)(B)(ii) of the Act and 21 CFR 515.22(c)(2). Based on the results of the July 2004 inspection, evaluated together with the evidence before FDA when the Medicated Feed Mill License was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies. This letter constitutes official notification under the law.

You should notify this office, in writing, within fifteen (15) working days of the receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the cGMP violations and prevent their recurrence. If corrective action cannot be completed within 30 working

days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Nadine Nanko Johnson, Compliance Officer, at the above address.

Sincerely,

for Charles W. Sedgwick
District Director
Kansas City District